

March 1, 2005

Mr. Gary M. Jackson
Assistant Administrator for Size Standards
Office of Size Standards
U.S. Small Business Administration
409 Third Street, S.W.
Washington, D.C. 20416

RIN 3245-AF22 -- Small Business Size Standards; Selected Size Standards Issues

Dear Administrator Jackson:

The California Healthcare Institute (CHI) appreciates the opportunity to respond to the U.S. Small Business Administration's (SBA's) request for comments on its December 3, 2004 Advance Notice of Proposed Rulemaking (ANPRM) on the Small Business Innovation Research (SBIR) program (69 Fed. Reg. 70197).

CHI represents the full biomedical sector of the California economy and unites more than 225 of California's leading life science firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one third of all U.S. biotechnology and medical device firms, turning scientific discoveries into medical products at an unprecedented rate. California biomedical companies lead the nation in bringing to market frontline therapies for diseases such as AIDS, cancer, stroke, and diabetes. This cutting-edge research is reflected in California's place as the largest recipient of SBIR awards-- totaling 1197 awards and nearly \$300 million in FY 2002.

The ANPRM seeks input on whether SBA should disregard its affiliation rules for SBIR program purposes and allow business concerns that are majority owned or controlled by a VCC to be eligible for SBIR awards, regardless of any affiliations arising from the ownership and control of the VCC.

CHI notes that SBA recently issued a Final Rule (69 Fed. Reg. 70180) on a related topic. That Final Rule allows a concern that is at least 51% owned and controlled by another for-profit business concern to participate in the SBIR program so long as that firm is itself at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. This change would seemingly permit venture capital ownership of a SBIR awardee, but only if the VCC owned and controlled 51% of the SBIR awardee and the VCC itself was 51% owned and controlled by individuals.

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CHI supports greater participation by small California biomedical companies in the SBIR program and appreciates SBA for seeking public comment on the ANPRM. However, CHI believes that many small biomedical companies are excluded from the SBIR program because of SBA's requirement that SBIR awardees be owned by "individuals," which has been interpreted to mean only "human beings." CHI believes the scope of the ANPRM should be broadened to include corporations and other artificial entities in the definition of "individuals" in 13 C.F.R. § 121.702. Thus, neither SBA's Final Rule nor the ANPRM address the fundamental obstacle to participation of promising small biomedical companies in the SBIR program.

Many Small Biomedical Companies Are Excluded From the SBIR Program

CHI urges SBA to recognize that the biomedical industry is unique. Before most biomedical products can become commercially available, years of work and hundreds of millions of dollars of capital are required to complete testing and gain product approvals. Because of the large amount of capital required to bring a biomedical product from conception to the marketplace, many small biomedical firms seek venture capital funding early in the product development cycle. Because of the significant funding required to bring biomedical products to market, very few biomedical companies are capable of commercializing their technologies without significant VCC backing. Therefore, venture capital becomes the life-blood of many small biomedical companies focused on capital intensive research and development. For example, in 2003, 43% of the total \$5 billion biomedical venture capital dollars in the U.S. went to California companies.

Because of the large amounts of funding required to bring biomedical products to market, a single venture capital investor may not invest sufficient amounts to give it a majority ownership position in a small biomedical company. Thus, start-up companies turn to multiple funding sources and often a *combination* of venture firms will together own more than 51% of the company. When no *single* VCC owns or controls the firm, SBA's affiliation rules do not come into play, thus the VCC investment does not in and of itself disqualify the small company. Thus, disregarding affiliation with those VCCs may have limited or no impact on SBIR eligibility. However, because SBA has interpreted "individual" to exclude corporate entities, a small business that is majority owned by *multiple* VCCs will not qualify, even under the limited exception included in the Final Rule issued on December 3, 2004.

SBA Should Amend its Eligibility Requirements to Reflect Congress' Intent to Encourage VCC Investment in Small Businesses

Congress clearly intended for venture-backed companies to be eligible to receive SBIR grants. First, the stated purpose of the Small Business Innovation Development Act was to: (i) increase the amount of Federal research and development support for highly innovative small businesses, thereby bolstering the competitive position of the United States, and (ii) attract private capital to commercialize the results of Federal research.^{[1/](#)}

^{[1/](#)} See S. Rep. No. 97-194, 97th Cong., 1st Sess. 1981, *reprinted in*, 1982 U.S.C.A.A.N. 512.

Second, when Congress enacted the SBIR program in 1982, it very clearly recognized and endeavored to encourage the symbiotic relationship between VCCs and small technology firms. For example, there is an entire section of the relevant Committee Report detailing the importance of encouraging private investment. Indeed, the Committee concluded that:

providing small firms with R&D seed money ... will encourage additional private investment in these firms. The agency-wide SBIR program outlined in the legislation should facilitate the ability of participating firms to attract venture capital as well as other financial commitments from the private sector.^{1/}

Congress viewed the SBIR program as providing the necessary “proof of concept” to encourage venture capital investment in promising small businesses seeking to bring products from the laboratory to the marketplace. Moreover, Congress even went so far as to provide

special consideration in the funding review of Phase II proposals to applicants who are successful in attracting private capital commitments to pursue commercial applications of the Federal research. This special consideration is given by awarding extra points of merit to those proposals that have attracted private sector commitments for follow-on funding.^{2/}

Thus, Congress created a preference for companies that attracted venture capital investment in Phase II of the program. SBA’s current policy of excluding venture-backed firms from the SBIR program is clearly at odds with stated Congressional purposes.

Recommended Changes to SBIR Eligibility Requirements

As explained above, the exclusion from the affiliation rules proposed in the ANPRM will have little, if any, practical effect for many California biomedical firms, because the fundamental flaw in the regulation requiring 51% ownership by natural persons will remain.

The ANPRM specifically seeks alternative approaches that may assist small business concerns in obtaining and utilizing VCC funding while participating in the SBIR program. CHI recommends that SBA adopt a rule that addresses the actual ownership structure of most small biomedical companies. Specifically, CHI suggests that 13 C.F.R. § 121.702 be clarified to permit both natural and artificial persons, including VCCs, to count toward the 51% U.S. ownership and control requirement. Revising the definition of eligible persons will ensure that small biomedical companies that are successful in attracting VCC investment will remain eligible for SBIR awards. Further, this clarification would reflect Congress’ original intent when it established the SBIR program, and allow federal agencies to continue to support the innovative research being conducted by California’s small biomedical companies.

Finally, CHI suggests that the VCC issue be addressed expeditiously and separately from the SBA’s initiative to restructure the small business size standards, given that the two issues are distinct.

^{1/} *Id.*
^{2/} Committee Report at 7-8.

In summary, CHI shares SBA's concern that only genuine small businesses with promising technologies should receive SBIR awards. However, the continued reliance on a rule essentially requiring 51% individual ownership is counterproductive and will actually exclude many deserving small biomedical businesses from the SBIR program. The simple answer to the current problem is to define the term "individuals" in the present regulation to include both natural and artificial persons. We also request that this change be made retroactive, to allow SBIR awardees whose grants have been revoked under the current interpretation of the regulations, the opportunity to continue to receive funding from this important source.

Please contact Todd Gillenwater, CHI Vice President for Public Policy, at (858) 551-6677 if you have any questions about CHI's comments.

Sincerely,

A handwritten signature in black ink that reads "David Gollaher". The signature is fluid and cursive, with the first name "David" and last name "Gollaher" clearly distinguishable.

David L. Gollaher, Ph.D.
President & CEO